

ONE HUNDRED TWELFTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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WASHINGTON, DC 20515-6115

Majority (202) 225-2927
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January 26, 2012

Ms. Marilyn Tavenner
Acting Administrator and Chief Operating Officer
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Ms. Tavenner:

We are concerned that, in spite of numerous requests, the Centers for Medicare and Medicaid Services (CMS) has failed to address the issue of ensuring that additional safety standards are in place for those suppliers who wish to enter bids for contracts to supply Negative Pressure Wound Therapy (NPWT) products to Medicare beneficiaries in Round 2 of the Medicare Competitive Bidding Program (CBP).

During the two weeks that Round 1 was in effect prior to its suspension by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), there were a number of winning suppliers who backed out of the program after signing contracts because they were unable or unwilling to deliver the level of training and support required in providing advanced wound care. Without access to appropriate products provided by competent suppliers, many clinicians in those bidding areas were unable to discharge patients from hospitals to home on a timely basis. Without appropriate NPWT accreditation, we fear this problem could happen again.

In order to ensure that manufacturers and suppliers of NPWT who submit bids are properly qualified and will be able to provide the level of training and support needed in the management of patients with complex wounds, we ask that CMS only consider bids from manufacturers and suppliers who have gone through an accreditation process that includes a pre-survey NPWT accreditation checklist, such as the one developed by the Alliance for Wound Care Stakeholders—a consortium of physician, clinical and patient organizations.

We feel that the additional standards included in the checklist for NPWT are entirely appropriate. In the “Durable Medical Equipment Prosthetics, Orthotics and Supplies (DMEPOS)

Quality Standards" published by CMS in October 2008, CMS acknowledged that the basic standards were not enough for three categories of DMEPOS and imposed additional quality standards to: respiratory equipment, supplies and services; manual wheelchairs and power mobility devices, including complex rehabilitation and assistive technology; and custom-made orthotics, prosthetic devices, somatic, ocular and facial prosthetics and therapeutic shoes and inserts. Although NPWT is at least as complex as these products, there are no additional standards or checklists for potential NPWT bidders. The Food and Drug Administration (FDA) has also recommended that the use of NPWT in the home require higher levels of training and 24/7 patient support by accredited suppliers.

In addition, CMS should inform prospective bidders of the need to meet these additional standards prior to bid submission. Allowing suppliers who are unaware of the complexities of providing NPWT and who do not meet the requirements set forth in the competency checklist to bid for NPWT contracts could again cause substantial interruptions in access to advanced wound care, leading to delays in hospital discharges and needless hospital readmissions, resulting in increased costs, rather than savings to the Medicare program. More importantly, Medicare beneficiaries could have their safety and well-being jeopardized.


Since the 60 day Round 2 bidding window is scheduled to open on January 30, 2012, we strongly request that CMS address this issue immediately.

We appreciate your urgent attention to this issue, will work with you in any way possible to resolve this matter and will continue to work with you toward the successful implementation of the Competitive Bidding Program. Please contact Committee Majority staff John O'Shea at (202) 225-2927 or Julie Hart in Rep. Gonzalez's office at (202) 225-3236 if you have any questions.


Sincerely,



Fred Upton
Chairman



Joseph R. Pitts
Chairman
Subcommittee on Health



Michael C. Burgess
Vice Chairman
Subcommittee on Health



Charles A. Gonzalez
Member

cc: The Honorable Henry A. Waxman, Ranking Member